

Notice of Allowability

Application No.

10/043,471

Examiner

David A Reifsnyder

Applicant(s)

COOK ET AL.

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication filed on July 30, 2003 and Examiners Interview December 4, 2003.
2. ☒ The allowed claim(s) is/are 1-28 (re-numbered as claims 1-15, 19, 16, 17, 20, 18 and 21-28, respectively).
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1 <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>20031204</u> . |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

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INTERVIEW SUMMARY and EXAMINERS AMENDMENT

INTERVIEW SUMMARY

Had an Examiner-Initiated Interview with Raymond E. Stauffer on December 4, 2003. It was agreed that non-elected claims 29-32 would be canceled by Examiner's Amendment. Claims 29-32 were non-elected with traverse by the applicant in a paper received on July 31, 2003. Of course the applicant may claim the subject matter of the cancelled claims in a divisional application. Furthermore, the priority claim on page 1, paragraph 1 needed to be changed because a non-provisional application can only claim the benefit of priority of a provisional application.

EXAMINERS AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Raymond E. Stauffer on December 4, 2003.

The application has been amended as follows:

In The Specification

Page 1, paragraph 1 of the specification has been replaced with the following amended paragraph:

This application claims the benefit of priority of ~~based on, and is a continuation-~~
~~in part of,~~ provisional application Serial No. 60/262,443, filed January 16, 2001, the
contents of which are incorporated herein by reference in their entirety.

In The Claims

claims 29-32 have been canceled.

REASONS FOR ALLOWANCE

The main reason for the allowance of claims 1-28 is the instantly claimed method of removing at least one population of **target pathogens** from a biological fluid sample, comprising:

(a) providing a plurality of high density microparticles having bound thereto a reactant which specifically binds to the **target pathogen**, and having a density sufficient to provide differential gravity settling of the **target pathogen** from the sample;

(b) mixing a portion of the sample with the microparticles to bind the microparticles to the **target pathogen**;

(c) settling the microparticles with the **bound pathogen** in the sample to produce a supernatant substantially free from the **bound pathogen, where the settling is accomplished primarily by gravity**; and

(d) separating the **microparticles bound to the pathogen** from the supernatant.

The closest prior art of record (i.e. Coulter et al.) discloses a method of removing at least one population of **target particles** from a biological fluid sample, comprising:

(a) providing a plurality of high density microparticles having bound thereto a reactant which specifically binds to the target particle and having a density sufficient to provide differential gravity settling of the **target particles** from the sample;

(b) mixing a portion of the sample with the microparticles to bind the microparticles to the **target particles**;

(c) settling the microparticles with the **bound particles** in the sample to produce a supernatant substantially free from the **bound particles, where the settling is accomplished primarily by gravity**; and

(d) separating the microparticles **bound to the particles** from the supernatant.

Coulter et al. fails to disclose or fairly suggest that his target particles can be pathogens.

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Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Giaever who discloses a method of removing at least one population of target pathogens (e.g. viruses or bacteria) from a biological fluid sample, comprising: providing a plurality of high density microparticles having bound thereto a reactant which specifically binds to the target pathogen (e.g. viruses or bacteria), mixing a portion of the sample with the microparticles to bind the microparticles to the target pathogen (e.g. viruses or bacteria); and magnetically separating the microparticles bound to the pathogen (e.g. viruses or bacteria) from the fluid sample.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A Reifsnyder whose telephone number is (703) 308-0456. The examiner can normally be reached on M-F 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda M Walker can be reached on (703) 308-0457. The fax phone


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number for the organization where this application or proceeding is assigned is (703)
872-9306.

Any inquiry of a general nature or relating to the status of this application or
proceeding should be directed to the receptionist whose telephone number is (703) 308-
3601.


David A Reifsnyder
Primary Examiner
Art Unit 1723

DAR